K092513

GENOSS

OCT - 9 2009

510(k) Summary

30th June, 2009

1. Company

	Submitter
Name	Genoss Co., Ltd.
Address	Gyeonggi R&DB Center 1F, 906-5 Iui-dong, Suwon-si Yeongtong-gu, Gyeonggi-do, 443-766, Korea
Phone / Fax	+82 31 888 5100 / +82 31 888 5105
Contact person	Kim, Yookang / QA ykkim@implantium.com

2. Device Name

Proprietary name: Rainbow Block
Common name: Dental frame material for Dental prosthesis
Classification name: Porcelain, powder for clinical use

3. Predicated Device

K061851 Zirkonzahn Ice
K063511 Ceramill Zi Blank

4. Description

Rainbow Block is a dental ceramic made out of zirconia. Rainbow Block is milled into cores for teeth and then is fired in the furnace to harden of ZrO_2. Then the core is layered with porcelain to make a finished tooth.

GENOSS

5. Indication for Use

Rainbow Block is used in the manufacture of a dental core through milling by machine (MAD/MAM or CAD/CAM) followed by sintering.

6. Review

Rainbow Block has the similar technological characteristics as the predicate devices; Main material, Indication for use and design.

Rainbow Block has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusions

Based on the information provided in this premarket notification of Genoss Co., Ltd. concludes that Rainbow Block is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Genoss Company, Limited
C/O Dr. Eunkyung Son
Dentium USA
11075 Knott Avenue, Suite A
Cypress, California 90630

OCT - 9 2009

Re: K092513
Trade/Device Name: Rainbow Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 5, 2009
Received: August 17, 2009

Dear Dr. Son:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GENOSS

Indications for Use

510(k) Number: K092513

Device Name: Rainbow Block

Indications for Use:

Rainbow Block is used in the manufacture of a dental core through milling by machine (MAD/MAM or CAD/CAM) followed by sintering.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ron Mylay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092513